

### REMARKS

Claims 62-125 are pending. By the foregoing amendment, claims 29-61 have been canceled without prejudice or disclaimer, and new claims 62-125 have been added. Support for the new claims is found in the specification, *inter alia*, at page 10, line 16 to page 11, line 2; page 20, line 8 to page 21, line 8; page 29, lines 10-12; and Examples 1-7. No new matter is added.

#### November 20, 2001 Personal Interview

As an initial matter, Applicant wishes to thank Examiner Colaianni for the courtesies extended to its undersigned representative during a personal interview on November 20, 2001. During the interview, a copy of the article, "Tobacco Specific Nitrosamines in Some Nigerian Cigarettes," was given to Mr. Colaianni. Apparently, the copy originally submitted together with the June 12, 2001 supplemental information disclosure statement submission became separated from the submission. Consideration of this document is respectfully requested.

The preambles of new independent claims 62, 66, 72, 76, 82, 86, 92, 96, 102, 108, 114, and 120 each point out that nitrosamine formation is substantially prevented "by treating the tobacco plant after the yellowing stage." Mr. Colaianni requested this language during the November 20, 2001 interview. This language simply clarifies that the "susceptible state" previously recited in claims 29-61 occurs after the yellowing stage, as described in the specification, *e.g.*, at page 12, lines 7-17 and Examples 1-7. The amendment thus does not narrow the scope of the claims.

#### Rejection Under the Doctrine of Obvious-Type Double Patenting

Claims 29-61 stand rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-22 of U.S. Patent 6,202,649. A terminal disclaimer is submitted herewith pursuant to 37 C.F.R. § 1.321(c), which is believed to obviate this ground of rejection.

#### Rejection Under 35 U.S.C. 112, Second Paragraph

Claims 29-61 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the invention. The Office Action contends that the comparison of nitrosamine content to that in tobacco made from the same crop

but which was cured in the absence of steps designed to reduce nitrosamine content, is indefinite. Although Applicants respectfully traverse this rejection, in an effort to advance prosecution, claims 29-61 have been canceled without prejudice. Accordingly, this rejection is now moot.

Rejections Under 35 U.S.C. §§ 102 and 103

Claims 29, 31-32, 39, 41-42, 44-46, 48-49, 55, 57-58, and 60-61 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Azumano U.S. Patent 3,939,227 ("Azumano"). Claims 30, 40, 47, and 56 stand rejected under U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over Azumano. Claims 33-35, 43, 53-54, and 59 stand rejected under U.S.C. § 103(a) as being unpatentable over Azumano in view of Wilson U.S. Patent 3,664,034 ("Wilson '034"). Claims 36-38 and 50-52 stand rejected under U.S.C. § 103(a) as being unpatentable over Azumano in view of Wilson U.S. Patent 3,503,137 ("Wilson '137"). By the foregoing amendment, claims 29-61 have been canceled. Each of these rejections is respectfully traversed insofar as it may be applied to new claims 62-125.

Azumano discloses a curing barn having automatic temperature and relative humidity control. Azumano identifies the two conventional periods of curing: a first period that includes the coloring (yellowing) stage and a second period that includes the leaf-drying and stem-drying stage (column 1, lines 23-26). Azumano discusses the coloring stage (first period) at column 10, line 59 to column 11, line 1:

During this [coloring] stage, the temperature and the amount of oxygen are maintained best suited for respiration. A principle purpose of this coloring stage is to increase the leaf temperature and thereby to facilitate respiration by circulation of hot air at a high humidity. The hot air at a high humidity has a heat quantity sufficient to control desiccation of tobacco leaf temperature.

(emphasis added). Azumano's reference to "respiration" in the context of coloring refers to the enzymatic activity in the leaf that is responsible for coloring. As recognized by Azumano, it is necessary to control desiccation (i.e., avoid rapid moisture loss) during the coloring stage by maintaining high humidity to facilitate such enzymatic activity. Otherwise, the leaf will not undergo coloring and its green color will be locked in.

Azumano's description of the coloring stage is consistent with techniques conventionally used for coloring, namely recirculating hot air at high humidity to enable the leaf to change in color from green to yellow through enzymatic activity. The subject application demonstrates that tobacco-specific nitrosamines are primarily formed after the yellowing stage.

The Azumano barn is equipped with a leaf drying system having an air-inlet opening and closing device. Azumano discloses that an object of the leaf drying system is "to slowly change the mixing ratio of the fresh air taken in and, thereby maintaining the chamber humidity at a proper level while advancing a successful drying operation." (column 3, lines 32-35) (emphasis supplied). As Azumano describes at column 1, lines 10-15, "unless the yellow coloring and the curing process is carried out with a proper adjustment of the dehydration speed and drying or curing temperature which does not destroy the cell or leaves, deterioration of the quality of the cured leaves will be the result."

According to Azumano, during the leaf drying stage the inlet port (10) and outlet port (14) are progressively opened such that the dry bulb temperature is slowly increased, i.e., relative humidity is slowly decreased (column 11, lines 6-53). Azumano refers to the point at which the inlet and outlet ports are fully opened as the beginning of the "true drying process" (column 11, line 44).

Azumano does not address nitrosamine formation. Azumano provides no specific directions that could be relied on to conclude that the operation of the curing barn would inherently prevent nitrosamine formation. The curing conditions described by Azumano do not in any way take into consideration microbial activity, a primary mechanism by which nitrosamines are formed in tobacco. Azumano's silence on the particular parameters used for leaf drying makes it impossible to conclude that the prevailing conditions differ from conditions that would be present during conventional tobacco curing. It is widely recognized that nitrosamines are formed in tobacco under such conventional curing conditions, primarily by way of microbial activity in which anaerobic microbes present on the tobacco leaf use nitrates as an oxygen source, yielding nitrites that in turn react with tobacco alkaloids to form nitrosamines.

Wilson '034 is cited as describing tobacco varieties recited in the dependent claims, and as describing a fan having a rated capacity of 50-120 CFM. With respect to airflows using during leaf drying, Wilson '034 discloses, "the rated capacity of the motor driven fan is utilized

only during the later leaf drying and stem drying stages of the curing process." (column 5, lines 31-32, see also column 4, lines 73-75). Like Azumano, Wilson '034 follows the convention of slowly changing from coloring to drying (*see, e.g.*, column 5, lines 32-50), and does not in any way address microbial activity. Thus, even if Azumano and Wilson '034 were somehow combined, the skilled worker would not have been led to use the higher airflows during early stages of leaf drying, during which the tobacco is in a state susceptible to nitrosamine formation via microbial activity. Wilson '034 does not describe curing tobacco under conditions for which it can be concluded that the formation of nitrosamines inherently would be substantially prevented. Wilson '034 fails to remedy the deficiencies of Azumano.

Wilson '137 is cited as describing curing tobacco under preselected humidity profiles. As illustrated in Fig. 8, Wilson '137 follows the convention of slowly changing from coloring to drying, *i.e.*, high relative humidity is present during coloring and the initial stages of leaf drying. Wilson '137 fails to describe or suggest avoiding anaerobic conditions during leaf drying, and fails to describe or suggest conditions for which it can be concluded that the formation of nitrosamines inherently would be substantially prevented. Wilson '137 thus fails to remedy the deficiencies of Azumano.

#### CONCLUSION

None of the prior art documents, taken alone or in any combination, describes or suggests a process of substantially preventing nitrosamine formation as is now claimed in claims 62-125. Favorable reconsideration and allowance of the subject application are respectfully requested.

Respectfully submitted,  
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